

## BOARD OF PHARMACY

### Final Statement of Reasons

Subject Matter of Proposed Regulations: Citations and Fines and Violations Subject to Citation and Fine

Sections Affected: 1775, 1775.1, 1775.15, 1175.2

Hearing Date: July 25, 2000

#### Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the expansion of its citation and fine authority, and no changes have been made.

#### Summary of Comments Received During the 45-Day Comment Period (May 12, 2000 to June 26, 2000)

Three comments were received during the comment period.

1. In a letter dated June 20, 2000 Orriette A. Quandt, Corporate Pharmacy Compliance Manager for Longs Drug Stores, provided several comments in opposition to the board's proposal on behalf of Longs Drug Stores.

Ms. Quandt stated that the board's proposal to cite and fine for any violation of the Pharmacy Law is problematic. Further, she stated that prevention is better achieved through education and mentoring than through sanction.

The board will continue to educate and mentor individuals to higher levels of performance. Expanding the citation and fine program does not end all other board enforcement activities. However, educating and mentoring are not enough. Laws are written because individuals engage in behavior that is harmful to others. While it is important for licensees to know and understand the law, without meaningful sanctions, sometimes even the most knowledgeable licensee will engage in prohibited behavior when it is in his or her interest to do so.

Ms. Quandt questioned whether the board is using the proposed regulation to increase revenue. She stated that current board activity appears to be moving away from using its inspectors for educating its licensees as few or no routine inspections are being conducted.

The board currently has a substantial surplus in the Pharmacy Board Contingent Fund and does not seek to add revenue to fund its operations. Furthermore, the board cannot increase expenditures without approval in the annual budget act passed by the Legislature.

Ms. Quandt stated that it appears the board is abandoning its emphasis on prevention and education by adopting this regulation.

This presumes that education and prevention are somehow at odds with official sanctions. The expansion of cite and fine authority does not require citations for all violations. Cite and fine is an intermediate sanction. The board continues to have admonition and formal disciplinary action available to use when appropriate.

The expansion of cite and fine does not require the end of all other board programs. The board continues to engage in a range of education and prevention activities. These include the quarterly publication of a newsletter that is mailed to all licensees, the recently redesigned website, and the availability of a duty inspector to answer questions on the telephone during regular business hours.

Ms. Quandt stated that because the board does not follow-up on each self-assessment form that pharmacies are required to complete, it is not fulfilling its primary duty of educating pharmacists.

Ms. Quandt's comment does not address the issues raised in this proposed regulation. The citation and fine program operates independently from the self assessment requirement.

The board's first and only duty is to protect consumers. To the extent that educational efforts are protective of public safety, then it has a responsibility to educate pharmacists. The board protects consumer safety through its primary duties of licensure and enforcement. The licensing exam given to pharmacists is a competency based exam designed to select those who have the skill and knowledge required to provide safe, quality care to patients. The enforcement program is designed to provide sanction and rehabilitation to those who fail to exercise the skill and knowledge demonstrated through the examination process. Ultimately it is the responsibility of all pharmacists to educate themselves. The board can and will make information available to its licensees, but the burden of learning falls squarely on the shoulders of the pharmacist and no one else.

Ms. Quandt stated that it is unfair for the board to have the authority to issue citations and fine pharmacists for violations that do not relate to the quality of their practice. Ms. Quandt stated that the board might use subjective assessments when considering the issuance of a citation and fine.

The board responds that the proposed regulation only grants the authority to issue a citation, it does not require the issuance of a citation and fine for all violations. Cite and

fine is being added as an intermediate sanction. The board will continue to have discretion to employ both admonition and formal disciplinary action when the circumstances are appropriate for those remedies. There are some violations that threaten the public safety, but do not directly impact the quality of care provided to patients (e.g., failure to file a discontinuance of business). The board has a public safety interest in the safe disposition of pharmacy stock after the closing of the pharmacy. Without filing this form, the board has no information regarding this transaction.

Ms. Quandt stated that because aspects of the Pharmacy Law are complex and violations due to misunderstandings of the law are easy to make, this regulation permits the board to issue a citation based on subjective assessments that are unfair.

First, the board continues to retain discretion regarding the imposition of appropriate sanctions and remedies. The board will apply citation and fine authority as an intermediate sanction, and does not foresee that citations will be issued for every minor violation. Moreover, the proposed regulation requires two members of the board to meet in public to issue a citation to a pharmacy or pharmacist (except for continuing education violations and failure to file a discontinuance of business notice). This requirement necessarily limits the number of citations issued.

Second, the fact that Pharmacy Law is complex and can be difficult to interpret does not relieve the pharmacist of the duty to grapple with those complexities and to seek guidance when there is a question. Pharmacists are professionals who are expected to apply complex concepts in the safe and appropriate delivery of pharmaceutical care. The board provides a duty inspector who is available to take queries by phone during regular business hours.

Third, parties subject to citations and fines by the board have the right to appeal any board decision and those sitting in judgement of the appeal have the authority and obligation to overturn fines that are arbitrary, unfair or violative of the respondent's rights.

Ms. Quandt questioned the utility of publishing statutes and regulations in the lawbook (published annually) and the *Script* (the board's quarterly newsletter) without added direction or interpretation.

The board responds that whether the laws governing pharmacists are clear is immaterial to the question of cite and fine authority. Clarity of the violation relates to the decision to pursue sanctions. The nature of the sanction applied is determined by the severity of the alleged violation, not the nature of the evidence supporting the allegation. Moreover, the board has a vigorous legislative and regulatory program to update and clarify existing statutes and regulations. The public meeting of the board's legislation and regulation committee (which occurs each October) was established to provide the regulated community with an opportunity to comment on these issues and identify unclear, conflicting or outdated requirements.

Ms. Quandt stated that the board should not assume the added workload of this cite and fine authority without first clearing the backlog of cases.

The board responds that expansion of cite and fine authority does not increase the number of substantiated cases and will not impact the board's efforts to close cases on a timely basis. The board must still have a case that substantiates the alleged violation before proceeding with a citation. Issuing a citation does entail more staff work than a routine appearance before a compliance committee or office conference (the prior destination of most new cite and fine complaints under this proposal) but that work is not performed by the inspectors or other staff responsible for closing cases. Compliance with the Pharmacy Law is an item of primary importance to the board. This proposed regulation is squarely aimed at increasing compliance by imposing meaningful and appropriate sanctions on violators.

Ms. Quandt stated that additional cite and fine authority will discourage the reporting of errors under Senate Bill 1339 (Figueroa) which is sponsored by the board.

The board responds that under the provisions of SB 1339, the board will not receive medication error reports. Rather, the bill requires that pharmacies have quality assurance programs to document medication errors and use that information to reduce the incidence of medication errors. It is not the intent of the board to use this program to punish pharmacists. In fact, the initial version of the legislation explicitly stated that the board could consider compliance with this requirement as a mitigating factor in medication error cases brought to the board by other means. However, that provision was removed from the bill at the request of industry representatives, in favor of including such a provision in the regulations implementing the program.

Ms. Quandt stated that the board should focus on cases where there is clear and concise evidence of a violation, not meritless, non-jurisdictional cases.

The board agrees with this comment and responds that according to the dictates of California law, the board only pursues disciplinary cases where there is clear evidence of a violation. Absent such evidence, no disciplinary action is taken. Again, the addition of cite and fine authority is a question of appropriate sanctions, not of the evidence of a violation. Furthermore, by definition, the board cannot take disciplinary action without jurisdiction over the matter in question. However, whether the complaint is within the jurisdiction of the board cannot be ascertained without at least a preliminary investigation.

The board specifically choose not to create a list of specific code sections whose violation would be subject to a citation and fine because such an approach denies the flexibility needed for effective enforcement. Currently, the board has the ability to cite and fine for only a few violations and after five years, has determined that the public safety would be enhanced if the board could cite and fine for all violations. Furthermore, a specific list

imposes added burdens on the board, the Department of Consumer Affairs, and the Office of Administrative Law by requiring individual regulation proposals when the board wishes to add a violation to its citation and fine authority or when new laws are created.

Ms. Quandt stated that the proposed regulation places form over substance and therefore places an unnecessary burden on pharmacists.

Citation and fine authority imposes no new requirements on pharmacists. They must follow the same law and any violations of those laws must be substantiated before the board may take disciplinary action of any kind. If there are elements of existing law that Ms. Quandt, Longs Drug Stores or any other individual finds to be unnecessary or fail to provide for public safety, then the affected parties should pursue the repeal of those provisions. Each year, the board pursues statutory changes to clarify the law or when there is no need or a given mandate. The adoption of this proposed regulation will neither increase nor decrease the number of standards with which pharmacists must comply. The board pursues all complaints that it receives as part of its mandate to protect the public.

2. In a letter dated June 26, 2000, John Cronin, General Counsel to the California Pharmacists Association, stated his opposition to the proposed regulation.

Mr. Cronin stated that the board does not use the full scope of its existing disciplinary authority. Specifically, the CPhA believes that the board should use the license renewal process to remedy outstanding notices of correction. The CPhA would rather deny renewal of licenses for those who fail to correct violations than pursue the disciplinary process.

Board counsel has examined the legal authority proffered by Mr. Cronin in support of this contention. The board cannot refuse renewal of a license on the grounds proposed by Mr. Cronin because it eliminates due process protections and would require the board to deny an individual or entity to operate without a hearing.

The essential purpose of this regulation is to provide the board with additional enforcement options. The initial statement of reasons published for this proposal states,

“Current regulations do not provide the board with appropriate options for violations that warrant more severe sanction than admonition but are not appropriate for formal disciplinary action.”

Expanded cite and fine authority is designed to be such an intermediate sanction. Taking action against a license requires an administrative hearing where the board is represented by the Attorney General, and an administrative hearing is a lengthy and costly process. This does not present an intermediate option as cite and fine does.

Mr. Cronin stated that the board should correct existing deficiencies and problems in the

enforcement program before pursuing expanded cite and fine authority. Specifically, until pharmacy inspectors can be hired and routine inspections resumed, no expansion of any program should be considered.

The board's proposed expansion of its cite and fine authority does not create meaningful additional workload for inspectors. No new cases will be generated by the expansion of the board's cite and fine authority. Rather, cite and fine gives the board another option when imposing sanctions for substantiated violations. There is no logical connection between the need for expanded authority and the resumption of routine inspections or having a full complement of inspectors on staff; however, the resumption of routine inspections would almost certainly increase the number of cases brought before the board. For those cases that are substantiated, in whatever number or from whatever source, the board will have another option to discipline violators.

Mr. Cronin stated that there is a lack of compliance with the patient consultation requirements contained in OBRA 90.

The board responds that California law regarding patient consultation is significantly stronger than OBRA 90 requirements, so compliance with OBRA 90 is not the appropriate metric. Furthermore, the board is unaware of any systematic data that either supports or refutes the contention that pharmacies are not improving their compliance with patient consultation requirements.

Mr. Cronin expressed concern that the self assessment form will be the basis for new citations under the proposed regulation.

The self-assessment form and requirement are designed to be an educational tool and provide pharmacists with a tool that assists them in complying with the law. The questions asked on the form refer to general pharmacy operations issues, they do not solicit factual information of sufficient particularity to justify disciplinary action. Responses to the self-assessment questionnaire alone are not grounds for a citation. In fact, the self-assessment form describes the compliance issues that are a priority for the board and reduces possible ambiguities. Lastly, the self-assessment form is not forwarded by the pharmacy to the board. Therefore, the only circumstance where a self-assessment form would be evaluated is as part of an inspection. If there is a violation (other than a failure to complete the self-assessment as required), there will be tangible evidence of the violation whose value far exceeds any statement on a self-assessment form.

Mr. Cronin states that existing problems with the handling of disciplinary cases by the executive officer would be aggravated by the added authority granted to the executive officer to issue citations for certain violations.

All disciplinary cases filed by the board are based on investigations that reveal factual evidence of a violation of the law governing pharmacies. The board has the legal

obligation in formal disciplinary hearings to present clear and convincing evidence of a violation before any action can be taken. These cases are adjudicated either by members of the board or by an administrative law judge where the board is represented by the Attorney General's office. The layered review process and respondents' ample due process rights ensure that cases are handled fairly and fall within the board's legal authority.

Proposed citations for a pharmacist or pharmacy are reviewed by both the supervising inspector and a committee of the board. Under the proposed regulation, the executive officer could only issue citations for three specific violations that would affect either a pharmacy or pharmacist (continuing education violations and failure to file a discontinuance of business form) and unlicensed activity. It is unlikely, indeed almost impossible, for these provisions to be avenues for abuse by any single member or employee of the board.

Mr. Cronin states that the board should defer action, and any other major policy action, until the Governor can replace existing board members.

The board's staggered appointment schedule and limit of two terms of service is designed to create a constant low level of change among the members, and members are expected to remain active members until their appointments expire. There is no point at which a number of board members will be facing relatively imminent replacement. The timing of these appointments does not relieve the board of its responsibilities in either operations or policymaking. Furthermore, the consideration of the composition of the board has no bearing on the merits of expanded cite and fine authority.

3. In a facsimile transmission dated June 25, 2000, Steve Gray, representing Kaiser Permanente, made several suggestions regarding the proposed regulation. Mr. Gray did not oppose the regulation.

Mr. Gray stated that the rule should be amended to restrict cite and fine to repeated or particularly egregious violations.

The board responded that the purpose of expanding cite and fine authority is to provide the board with intermediate sanction. Repeated or egregious violations are commonly grounds for more severe disciplinary action.

Mr. Gray stated that the proposed rule should be amended to restrict cite and fine to those violations for which the public has no civil remedy and do not warrant referral to the Attorney General.

The board responds that such a restriction violates the essential purpose of the board. Licensing boards, including the Board of Pharmacy, are established to protect consumers and advocate their interest. The proposed change would have the perverse effect of preventing the board from issuing a citation in a case where a consumer was harmed and

instead direct the patient to go to court.

Mr. Gray stated that the potential exposure of the Pharmacist In Charge (PIC) to fines as the responsible party will discourage pharmacists from accepting PIC positions.

The board responds that pharmacies are required under California Law (Section 4113 of the Business and Professions Code) to designate a PIC who is responsible for the pharmacy's compliance with all federal and state laws relating to the practice of pharmacy. The board does subject the PIC to disciplinary action for violations of others under his/her supervision when those violations are related to a failure of supervision but not for actions solely attributable to others.

Mr. Gray stated that the rule should be amended to create a two hearing process for issuing citations. The first hearing would explore the facts and inform the respondent. The second hearing would permit the respondent to answer the allegations and bring other evidence to light before the citation is issued.

The board responds that the proposed regulation includes a requirement that the board include a summary of allegations to each individual prior to hearing. That summary provides the respondent with sufficient information regarding the alleged violation for a complete gathering of information by the respondent prior to the first hearing. There is no need for a second hearing in all cases. The board committee has the ability to conduct an additional hearing in those rare cases where it is needed to obtain additional information. To require two hearings for all violations would impose a greater burden on the pharmacist by having to attend both hearings.

Mr. Gray states that fines against a PIC, other than those for his/her own misconduct, should be limited to 50% of the fine against the licensee committing the violation.

The board responds that establishing such a strict guideline in regulation unnecessarily restricts the board's ability to match the fine to the nature of the violation. There are cases where the PIC is substantially responsible for the violation through an absence of adequate supervision or management and should be accountable. There are also cases where the PIC is not responsible at all. Strict guidelines in the regulation deny the board the discretion to make this essential judgment.

#### Summary of Comments Received During the Public Hearing July 25, 2000.

1. Alan Pope representing Longs Drug Stores referred to a letter dated June 12, 2000, from Orriette Quandt and himself, stating the opposition of Longs Drug Stores to the board's proposal.

Mr. Pope stated that the board's purpose is to educate pharmacists about the law. He added that the cite and fine regulation is a punitive type of measure.



The board's primary charge is public protection and the board will continue to educate and mentor individuals to higher levels of performance. Expanding the citation and fine program does not end all other board enforcement activities. However, education and mentoring are not enough. Laws are written because individuals engage in behavior that is harmful to others. While it is important for licensees to know and understand the law, without meaningful sanctions, even the most knowledgeable licensee will engage in prohibited behavior when it is in his or her interest to do so.

Mr. Pope stated that during the public comment period in April, Longs Drug Stores had mentioned that there wasn't a procedure in the proposed regulation for a notice of violation. Instead of issuing a citation, first and second offenses would receive progressive sanctions. He stated that without having some kind of notice provision, Longs Drug Stores opposes this proposed regulation.

The board has authority to issue notices of violation. A notice of violation is a written notice issued by a pharmacy inspector of a violation of the Pharmacy Law to a pharmacy of pharmacist. In fact, the proposed amendments to section 1775 (d) specifically reference notices of violation. Nothing in the proposed regulation repeals or reverses the board's authority to impose a variety of sanctions for a violation. These sanctions include admonition, citation and fine, probation, and the revocation of a license. The purpose of the regulation, as stated in the initial statement of reasons, is:

“Current regulations do not provide the board with appropriate options for violations that warrant more severe sanction than admonition but are not appropriate for formal disciplinary action.”

Mr. Pope stated that another issue that Longs Drug Stores has with the proposed regulation is that the cite and fine regulation should be limited to quality of practice issues. He added that licensing, consultation, etc., are the primary issues that the cite and fine is currently used for.

The board agrees with that Mr. Pope's assessment of the existing range of citations and fines available to the board. Current regulations restrict the board to issuing citations for violations relating to unlicensed practice, patient consultation and continuing education. The board has proposed this regulation to expand the range of violations subject to citation and fine.

The board disagrees with the contention that these are the only violations that impact the quality of care. There is a range of requirements in the Pharmacy Law that applies to the safe and sanitary handling and storage of prescription drugs that materially affect the quality of pharmacist's care.

Lastly, the board responded that the board's regulatory interest is not restricted only to patient care. The board is required to protect the public safety more generally. In fact,

section 4005 of the Business and Professions Code, which establishes the board's general rulemaking authority, specifically permits the board to adopt regulations "for the protection of the public." Restricting citation and fine to quality of care issues, ignores other important public safety issues for which the board is responsible.

Mr. Pope stated that the proposed cite and fine regulation is over-broad with respect to including all pharmacy law. He stated that the regulation should be limited to those areas of practice that really involve consumers. He stated that the board does not need the cite and fine authority to clean up a pharmacy and that there are other ways to enforce this.

The board believes that the proposed regulation does not apply to all "pharmacy law" which includes portions of the California Business and Professions Code, California Health and Safety Code, the U.S. Food, Drug and Cosmetic Act, the U.S. Controlled Substances Act and regulations adopted pursuant to any of those statutes. Rather, the regulation references "The Pharmacy Law" which is how Business and Professions Code, Division 2, Chapter 9 is cited (per Section 4000 of the Business and Professions Code). Furthermore, section 125.9 of the Business and Professions Code is cited as the principal authority for adopting the proposed regulation. That section restricts the scope of citation and fine regulations adopted by boards in the Department of Consumer Affairs to violations "of the appropriate licensing act or any regulation adopted pursuant thereto."

Mr. Pope stated his concern about the process for considering this proposal. He added that, after the informational meeting, held in April 2000, the regulation was referred to the Legislation and Regulation Committee for further consideration. Mr. Pope expressed concern that the public comments were not considered because the noticed regulation looked the same as the draft regulation released in advance of the informational meeting.

Before publishing the notice for this proposed regulation, the board conducted an informational meeting at the April 2000 meeting of the board. Interested parties were mailed a draft regulation in advance of that informational hearing. The informational hearing was held to solicit input in drafting the proposed regulation. In response to comments provided at that meeting, the board did clarify the process used by the board to issue citations and fines as stated in the proposed regulation. Most notably, the proposed regulation was amended to require the board to send a summary of the alleged violations to the licensee prior to the hearing considering the alleged violations.

Mr. Pope referred to the minutes of the Organizational Development Committee meeting in the July 2000 board meeting packet. In these minutes, it refers in the budget update to a full-time legal position that will permit the board to have an attorney present at committee meetings, board meetings and compliance meetings, and, once the expanded cite and fine regulations are in place, the attorney will sit in on these hearings. He added that, based on this language, the adoption of this regulation is a foregone conclusion. He asked where is the public comment? He stated that there has been none. The board took public comment to the committee and returned with the same regulation. He stated that the board should not use this process to promulgate regulations.

The board takes every reasonable step to assure meaningful public participation in the rulemaking process. This includes the extra effort to conduct a noticed informational meeting in April 2000 on draft regulations in advance of submitting the formal notice and a second public hearing was conducted in July 2000 as part of the formal rulemaking process. As noted in the response to the prior comment, the board did make some changes to the proposed regulation based on comment provided during the informational meeting.

The fact that the board has engaged in budget planning for the 2001/02 fiscal year based on the strategic objective of expanding citation and fine authority (as published in the board's 1999 strategic plan) should not be taken as a predetermined outcome. The administration requires the board (and all other state agencies) to submit budget change proposals reflecting anticipated changes in workload or increases in costs nearly one year in advance. Failure to submit a budget change proposal before the deadline results in deferring the proposed change for consideration to the 2002/03 budget cycle. If the regulation is not adopted by the board or fails to gain final approval, the budget change proposal can be withdrawn but it cannot be submitted after the deadline has passed.

Mr. Pope stated that the committee meetings should be opened to the public and should be noticed. He stated that the public meeting process is meaningless.

The board responded that it complies fully with both the Public Meetings Act and the Administrative Procedures Act. This comment does not address the essential issue at hand in the proposed regulation, but rather the board's organizational structure.

Mr. Pope stated that when there is a regulation such as this, that has significant impact on pharmacists, the board needs to consider public comment. He encouraged the board to reconsider the public comment previously heard and come back with a regulation that is more limited and fairer to the profession.

The board gives full and fair consideration to all public comment in the rulemaking process. That consideration is seen in the changes made to the draft regulation prior to publishing the formal notice. The board has considered the public comment provided and found that the proposed regulation best serves its stated purpose. The proposed regulation is fair to licensees. The board must prove by substantial evidence that a violation has occurred and the licensee retains his or her due process rights, including rights of appeal, under this proposal. The board's fundamental mission is the protection of public safety. The board is not the guardian of the profession of pharmacy, and stronger sanctions than warnings and education are sometimes needed.

Mr. Pope stated that there are no advocates for the public at the committee meetings. From the practitioner's perspective there need to be advocates at these committee meetings. He felt there could be a compromise that would not only to protect the consumer, but be fairer and more compliant with due process for the rights of individuals.

All board members are charged with acting as public advocates and protecting the public safety. Furthermore, the board has four members who are appointed as non-pharmacist public members. One of those public members serves on the Legislation and Regulation Committee that developed this regulation proposal and another serves as president of the board. All other members of the board are required to be licensed pharmacists. This mixed composition is intended to assure the full consideration of the public interest in board actions and to provide individual expertise in the matters considered by the board.

The board further responded that Mr. Pope's proposed changes to the board's proposed regulation (restricting the expansion of cite and fine authority to the failure to designate a pharmacist-in-charge) do not provide any due process protections not afforded under either the current regulation or the proposed regulation. It is unclear how Mr. Pope's proposed changes are more protective of public safety than the board's proposed regulation.

2. Ms. Orriette Quandt, representing Longs Drug Stores, also referred to the letter from Longs Drug Stores dated June 12, 2000, and stated the opposition of Longs Drug Stores to the proposed regulation.

Ms. Quandt stated that the issue she is most concerned with is the number of regulations in pharmacy law for which the board wants to issue citations. The sheer number of those regulations, makes it almost impossible for pharmacists to comply with all pharmacy laws.

The overwhelming majority of rules governing the practice of pharmacy are statutory requirements and compliance, regardless of their number, is not optional. The body of law that applies to the practice of pharmacy is substantial but it is written in plain English and the text of this law is readily available in a number of publications (including the pharmacy lawbook published by the board and provided to pharmacies each year) and on the internet. The board also provides a pharmacy inspector who is available during normal business hours to respond to any inquiries from pharmacists regarding their legal authority and obligations.

Ms. Quandt stated that pharmacists wish to comply with pharmacy law, but are unsure of the board's interpretation of the law.

The board has provided every pharmacy with an updated lawbook that contains the relevant portions of state law each year. If that source, and other board publications (such as a quarterly newsletter), do not provide sufficient clarity, the board makes a pharmacy inspector available by telephone to respond to questions from pharmacists. The pharmacist has a statutory obligation and professional duty to understand and comply with pharmacy law regardless of its clarity. Furthermore, the state licensing examination includes a segment that covers relevant aspects of California law.

Ms. Quandt stated that the board needs to educate and mentor pharmacists. Until the board can fulfill its fiduciary responsibility to undertake the education and mentoring process, the board needs to put this proposed regulation on hold.

The board will continue to educate and mentor individuals to higher levels of performance. Expanding the citation and fine program does not end all other board enforcement and educational activities. However, education and mentoring are not enough. Laws are written because individuals engage in behavior that is harmful to others. While it is important for licensees to know and understand the law, without meaningful sanction, even the most knowledgeable licensee will engage in prohibited behavior when it is in their interest to do so. Moreover, the board has only 21 inspectors. It is a practical impossibility for them to educate and mentor the state's 28,000 licensed pharmacists and the 6,000 pharmacies licensed by the board. As professionals, pharmacists and other board licensees need to educate themselves about the law governing their practice.

Ms. Quandt stated that in reviewing the board packet, it is obvious that the board has not conducted routine inspections. Ms. Quandt added that routine inspections are important for educating and mentoring pharmacists. Instead, the board's inspectors are now investigating complaints and licensees know that if an inspector appears they are investigating a complaint.

Routine inspections are an important component of the board's compliance efforts. The board has temporarily suspended routine inspections to devote its full attention on clearing the backlog of enforcement cases. The board will resume its routine inspection program in January 2001. However, there is no logical connection between the need for expanded authority for citation and fine and the performance of routine inspections.

Ms. Quandt stated that when pharmacists come before the Southern Compliance Committee or Northern Compliance Committee, many times those pharmacies have not been inspected for possibly five years, ten years, sometimes even longer. She added that routine inspections are a very important process the board should consider before it looks at expanding cite and fine. She added that once the board is doing routine inspections, the board should consider expanding cite and fine.

Expanded citation and fine authority gives the board another option when imposing sanctions for violations. There is no logical connection between the need for expanded cite and fine authority and the resumption of routine inspections. In fact, the resumption of routine inspections would almost certainly increase the number of cases brought before the board. For those cases that are substantiated, in whatever number or from whatever source, the expansion of cite and fine authority will provide the board with another option to discipline violators.

Ms. Quandt referred to violations involving a pharmacy's failure to designate a pharmacist-in-charge with the board. She stated that in talking to John Jones (a member of the Board of Pharmacy), he indicated that there was a problem in pharmacies designating a pharmacist in charge. She added that if the board has specific issues like this, the board should impose cite and fine only on these violations.

The difficulty in achieving compliance with the pharmacist-in-charge requirement was offered as an example demonstrating the difficulty posed by not having an intermediate sanction available. It is not the only situation that presents the need for an intermediate sanction. The board declined to enumerate specific code sections subject to citation and fine because the appropriate level of sanction is a function of the seriousness of the violation (e.g., is it a repeat violation, was someone injured, was there potential for injury, etc.) and the nature of the violation itself (e.g., what section of law was violated).

3. John Cronin, California Pharmacists Association (CPhA) referred to his letter dated June 26, 2000, stating the opposition of the CPhA to the proposed regulations.

Mr. Cronin stated that the Board of Pharmacy has made, on numerous occasions, commitments to provide educational services for enforcement and CPhA has not seen this. He added that until the board can do this with the licensees and pharmacies, with a full force of inspectors, cite and fine is premature.

The board has, from time to time, provided board inspectors to conduct continuing education courses on selected enforcement and compliance subjects. Each year the board staffs a booth at CPhA's educational fair and annual meeting. Such opportunities have been limited because of the heavy workload that board inspectors are carrying. The board will make inspectors available for such training courses as resources permit. However, the obligation of the board's licensees to comply with the law is not contingent on the availability of board inspectors to conduct continuing education programs through a single professional association.

Mr. Cronin stated that the CPhA believes that there are alternatives (denying renewal of licenses as indicated in his written comment to the board) to the proposed regulation and that it is not appropriate to expand cite and fine.

Board counsel has examined the legal authority proffered by Mr. Cronin in support of this contention. The board cannot refuse renewal of a license on the grounds proposed by Mr. Cronin because it eliminates due process protections and would require the board to deny an individual or entity to operate without a hearing.

Furthermore, the board stated that the CPhA fails to recognize the essential purpose of this regulation: to provide the board with additional enforcement options. The initial statement of reasons published for this proposal states,

“Current regulations do not provide the board with appropriate options for violations that warrant more severe sanction than admonition but are not appropriate for formal disciplinary action.”

Expanded cite and fine authority is designed to be such an intermediate sanction. Taking

action against a license requires an administrative hearing where the board is represented by the Attorney General's office. And administrative hearing is a lengthy and costly process. This does not present an intermediate option as does cite and fine.

Mr. Cronin stated that the initial statement of reasons does indicate what the board's attitude is about its enforcement role. He read from the initial statement of reasons, in part: "Referring many of these cases to the AG for administrative hearing is not effective because the licensee can correct the violation prior to hearing, rendering the process moot." He questioned the purpose of this comment. If the violation is corrected, you have succeeded.

The statement Mr. Cronin refers to from the initial statement of reasons highlights the reality that many licensees do not take corrective action until some material sanction is present and imminent. This regulation was proposed to provide an alternative material sanction whose threat is likely to induce corrective behavior more quickly and more efficiently.

Mr. Cronin stated that many licensees feel that the board's sole purpose is to punish pharmacists. Mr. Cronin added that this is the Department of Consumer Affairs, not the Department of Justice.

The board's purpose is not to punish pharmacists or other licensees. The board is obligated by statute to administer and enforce the Pharmacy Law. Professional discipline is an essential aspect of enforcement.

Mr. Cronin stated that the board needs to fix the other problems in the enforcement system, get a full force of inspectors, start routine inspections and use the alternatives available to enforce the rules.

The expansion of the board's cite and fine authority does not create meaningful additional workload for inspectors. No new cases will be generated by the expansion of the board's cite and fine authority. Rather, cite and fine gives the board another option when imposing sanctions for violations. There is no logical connection between the need for expanded authority and the resumption of routine inspections or hiring a full complement of inspectors; however, the resumption of routine inspections would almost certainly increase the number of cases brought before the board. For those cases that are substantiated, in whatever number or from whatever source, the board will have another option to discipline violators.

4. Mr. John Berger, pharmacist, stated that in the past, the Board of Pharmacy used to refer to voluntary compliance. He stated that he has not heard of this in the last few years. He added that the board should be out getting voluntary compliance, not doing things like issuing traffic tickets for violations.

The board does not consider voluntary compliance an adequate enforcement strategy in all cases. The board is constrained by the statutory options available to it when it imposes

sanctions for substantiated violations. Currently, the board's options are admonition, citation and fine, and formal disciplinary action. The board wishes to have a wider range of sanctions available so as to take the most appropriate action.

Mr. Berger stated that in the past, the inspector would inspect a pharmacy, note the problem, and the majority of time, the problem would be corrected.

The board notes that many pharmacists do correct violations upon notice by the board, but that the board must have sanctions available to take action against those who do not comply or those whose violations are too serious or severe for simple corrective action to be appropriate.

Mr. Berger stated that cite and fine will be a money-making thing and licensees are already afraid of the board.

The board currently enjoys a substantial surplus in the Pharmacy Board Contingent Fund and does not seek to add revenue to fund its operations via increased fine collections. Furthermore, the board cannot increase expenditures without approval in the annual budget act passed by the legislature. However, the board believes that its ability to cite and fine, especially when coupled with an active inspection program, may encourage greater compliance with the Pharmacy Law.

Mr. Berger stated that instead of filing a case five years after the facts happen, the board should file within one year of the event. Then publish it in the newsletter, and pharmacists would know that you can't do this.

The board agrees with the principle of filing cases as soon as possible. However, some cases are not brought to the board's attention until substantially after the acts have occurred. One virtue of the citation and fine process is its relative speed. Completing the process for a citation is faster than taking a case to an administrative hearing for formal disciplinary action against a license.

Local Mandate: None.

Business Impact: The board has determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives: The Board of Pharmacy determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.